Initial Approval Date: July 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Juvenile Idiopathic Arthritis Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Abatacept (Orencia®)
Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™)
Etanercept (Enbrel®, Erelzi™, Eticovo®)
Tocilizumab (Actemra®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, weight (if applicable), and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a rheumatologist.
- Patient must have had an adequate trial (at least 90 consecutive days) of or contraindication to methotrexate. If the patient has a contraindication to methotrexate, the patient must have an adequate trial of at least one other conventional therapy or contraindication to all conventional therapies listed in Table 2.[1]
- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of one of the following criteria:
    - Polyarticular Juvenile Idiopathic Arthritis (PJIA) with moderate to high disease activity, defined as:
        - Clinical Juvenile Disease Activity Score (cJADAS) score > 2.5.[1]
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Juvenile Idiopathic Arthritis (JIA) Agents. [2-9]

Medication	Indication(s)	Age	Dosing Limits
Interleukin-6 Inhibitors			
Tocilizumab (Actemra®)	PJIA	≥ 2 years	PJIA: IV: < 30 kg: 10 mg/kg every 4 weeks. ≥ 30 kg: 8 mg/kg every 4 weeks. SC: < 30 kg: 162 mg once every 3 weeks. ≥ 30 kg: 162 mg once every 2 weeks. SJIA IV: < 30 kg: 12 mg/kg every 2 weeks. ≥ 30 kg: 8 mg/kg every 2 weeks. SC: < 30 kg: 162 mg once every 2 weeks. ≥ 30 kg: 162 mg once every week.
Selective T-Cell Costimulation Blockers			
Abatacept (Orencia®)	PJIA	IV: ≥ 6 years SC: ≥ 2 years and at least 10 kg	IV: at 0, 2 and 4 weeks, then every 4 weeks thereafter < 75 kg: 10mg/kg, up to a maximum of 1,000 mg 75-100 kg: 750 mg > 100 kg: 1,000 mg SC: 10- <25 kg: 50 mg once weekly 25- <50 kg: 87.5 mg once weekly ≥ 50 kg: 125 mg once weekly
Tumor Necrosis Factor-Alpha (TNF-α) Blockers			
Adalimumab (Humira®)	PJIA	≥ 2 years and at least 10 kg	10- <15 kg: 10 mg SC every other week. 15- <30 kg: 20 mg SC every other week. ≥ 30 kg: 40 mg SC every other week.
Adalimumab-atto (Amjevita™)	PJIA	≥ 4 years and at least 15 kg	15- <30 kg: 20 mg SC every other week. ≥ 30 kg: 40 mg SC every other week.
Adalimumab-adbm, Adalimumab-adaz (Cyltezo™, Hyrimoz™)	PJIA	≥ 4 years and at least 15 kg	≥ 30 kg: 40 mg SC every other week.
Etanercept (Enbrel®)	PJIA	≥ 2 years	< 63 kg: 0.8 mg/kg SC once weekly, up to a maximum of 50 mg per dose. ≥ 63 kg: 50 mg SC once weekly.
Etanercept-szzs (Erelzi™, Eticovo®)	PJIA	≥ 2 years and at least 63 kg	≥ 63 kg: 50 mg SC once weekly.

SC: subcutaneous. IV: intravenous. PJIA: polyarticular juvenile idiopathic arthritis.

LENGTH OF APPROVAL (INITIAL): 12 months

APPROVED PA Criteria

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Prescriber must provide the following response measure:
  - Low disease activity, defined as cJADAS-10 score ≤ 2.5.[1]
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not be on another biologic or JAK inhibitor listed in Table 4. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 2. List of conventional therapy in the treatment of PJIA.[1]

Non-Biologic Disease-modifying antirheumatic drugs (DMARDs)	
Generic Name	**Brand Name**
Hydroxychloroquine	Plaquenil®
Leflunomide	Arava®
Methotrexate	Trexall®, Rheumatrex®, Otrexup®, Rasuvo®
Sulfasalazine	Azulfidine®

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Humira® (adalimumab)	Rituxan® (rituximab)
Amevive® (alefacept)	Hyrimoz™ (adalimumab-adaz)	Siliq® (brodalumab)
Amjevita™ (adalimumab-atto)	Ilaris® (canakinumab)	Simponi® (golimumab)
Cimzia® (certolizumab)	Ilumya™ (tildrakizumab-asmn)	Simponi Aria (golimumab)
Cinqair® (reslizumab)	Inflectra® (infliximab-dyyb)	Skyrizi™ (Risankizumab)
Cosentyx® (secukinumab)	Ixifi™ (infliximab-qbtx)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kevzara® (sarilumab)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Kineret® (anakinra)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Nucala® (mepolizumab)	Tysabri® (natalizumab)
Entyvio® (vedolizumab)	Olumiant® (baricitinib)	Xeljanz® (tofacitinib)
Erelzi™ (etanercept-szzs)	Orencia® (abatacept)	Xeljanz XR® (tofacitinib)
Eticovo® (etanercept-ykro)	Remicade® (infliximab)	Xolair® (omalizumab)
Fasenra™ (benralizumab)	Renflexis® (infliximab-abda)	

References:

1. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res 2019;71(6), 717-34. Available at https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Juvenile-Idiopathic-Arthritis. Accessed on 6/17/19.
2. Orencia (abatacept) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; March 2019.
3. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; December 2018.
4. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2018.
5. Cyltezo (adalimumab) [prescribing information]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals Inc: August 2017.
6. Enbrel (etanercept) [prescribing information]. Thousand Oaks, CA: Immunex Corp; May 2018.
7. Erelzi (etanercept) [prescribing information]. Princeton, NJ: Sandoz Inc; January 2018.
8. Eticovo (etanercept) [prescribing information]. Denmark: Samsung Bioepis; April 2019.
9. Actemra (tocilizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; April 2019.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
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